DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

7/22/97
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

July 14, 1997

WL-29-7

Inspection ID: 128124

Mr. Howard Berger
Chief Executive Officer
Northridge Diagnostic Center
8227 Reseda Boulevard
Reseda, California 91335-1247

Dear Dr. Berger:

Your facility was inspected on May 12, 1997, by a California State representative from Los Angeles County, Department of Health Services, Radiation Management under contract to the Food and Drug Administration (FDA). The inspection, as stated above, revealed that your facility failed to comply with the Quality Standards for Mammography (Standards), as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [redacted] MD.

2. The interpreting physician did not meet the requirement of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms: [redacted], MD.

The specific deficiency noted above appeared under the Level 1 heading on your Mammography Quality Standards Act (MQSA) Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance that is listed on the inspection report provided to you at the close of the inspection. The Level 2 noncompliance are:

3. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an

average of 40 patient examinations per month over 24 months: [redacted], MD.

4. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months: [redacted], MD.

5. The interpreting physician did not meet the initial training requirement of having 40 hours of continuing medical education in mammography: [redacted], MD.

6. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [redacted], MD.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.

- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. These requirements should be evaluated when you plan your corrective action(s). Therefore, you should consider the more stringent State requirements, if any.

Within 15 working days of receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (include technique factors), raw test data, and calculated final results, where appropriate; and
- example records that demonstrate proper recordkeeping procedures, if the noncompliances were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please send the original of your response to:

Robert W. Nicol
Compliance Officer
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

Also, send a copy to the California State radiation control office (Los Angeles County, Department of Health Services, Radiation Management) that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Sincerely yours,

Elaine C. Messa
District Director

cc: Ms. Bonnie Long, MQSA Inspector
County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont, Suite 300
Los Angeles, CA 90020